

Substitute form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

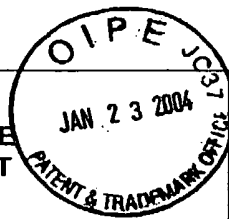
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Application Number	10/075,097
Filing Date	02/13/2002
First Named Inventor	Nnochiri N. Ekwuribe
Group Art Unit	1654
Examiner Name	Anish Gupta
Attorney Docket Number	9233-46

U.S. PATENTS AND PATENT PUBLICATIONS

Examiner Initials*	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code (if known)		
ADL	1	US-5,889,153		Suzuki et al.	03/30/1999

OTHER NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T
ADL	2	Aoki et al. "Chronic Intermittent Intravenous Insulin Therapy: A New Frontier in Diabetes Therapy" <i>Diabetes Technology & Therapeutics</i> 3(1):111-123 (2001)	
	3	Clement, Stephen "A Dose-Escalation Study of the Effects of Two Sequential Doses of Oral Modified Insulin on Blood Glucose Concentrations in Patients with Type 1 Diabetes Mellitus" <i>American Diabetes Association Annual Meeting (June 25, 2001) (Poster)</i>	
	4	Francis et al. "Polyethylene Glycol Modification: Relevance of Improved Methodology to Tumour Targeting" <i>Journal of Drug Targeting</i> 3:321-340 (1996)	
	5	Guzman et al. "Effects of Fatty Ethers and Stearic Acid on the Gastrointestinal Absorption of Insulin" <i>PRHSJ</i> 9(2):155-159 (1990)	
	6	International Search Report, PCT/US02/04440, 12/23/2003	
	7	Lindsay et al. <i>The Acetylation of Insulin Biochem J.</i> 121:737-745 (1971)	
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	11	Moghaddam, Amir "Use of polyethylene glycol polymers for bioconjugations and drug development" <i>American Biotechnology Laboratory</i> pp. 42, 44 (July 2001)	
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	13	Puskas et al. "Investigation of Chymotrypsin Digestion Profile of Orally Active Insulin Conjugate Him2" <i>AAPS PharmSci</i> 3(3) (2001) (Abstract)	
	14	Radakrishnan et al. "Stability and Physical Characteristics of Orally Active Amphiphilic Human Insulin Analog, Methoxy (Polyethylene Glycol) Hexanoyl Human Recombinant Insulin (HIM2)" <i>Proceed. Int'l. Symp. Control. Rel. Bioact. Mater.</i> 27:1038-39 (2000)	
	15	Shen et al. "(C) Means to Enhance Penetration; (3) Enhancement of polypeptide and protein absorption by macromolecular carriers via endocytosis and transcytosis" <i>Advanced Drug Del. Reviews</i> 8:93-113 (1992)	
	16	Sindelar et al. "A Comparison of the Effects of Selective Increases in Peripheral or Portal Insulin on Hepatic Glucose Production in the Conscious Dog" <i>Diabetes</i> 45:1594-1604 (1996)	
	17	Sirokman et al. "Refolding and proton pumping activity of a polyethylene glycol-bacteriorhodopsin water-soluble conjugate" <i>Protein Science</i> 12:1161-1170 (1993)	
	18	Torchilin, Vladimir P. "Immunoliposomes and PEGylated Immunoliposomes: Possible Use for Targeted Delivery of Imaging Agents" <i>Immunomethods</i> 4:244-258 (1994)	
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Examiner Signature

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FORM PTO-1449 U.S. Department of Commerce
Patent and Trademark Office

Attorney Docket Number
9233-46

Serial No.
10/075,097

LIST OF DOCUMENTS CITED BY APPLICANT

(Use several sheets if necessary)

Applicants: Ekwuribe et al.

Filing Date
February 13, 2002

Group
1646

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Examiner Initial		Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate
ADK	1.	2002/0160938	10/31/2002	Brandenburg et al.	A1		
ADK	2.	2003/0144468	07/31/2003	Ekwuribe et al.	A1		
	3.	2003/0087808	05/08/2003	Soltero et al.	A1		
	4.	2003/0083232	05/01/2003	Soltero et al.	A1		
ADK	5.	2003/0069170	04/10/2003	Soltero et al.	A1		
ADK	6.	2003/0060606	03/27/2003	Ekwuribe et al.	A1		
	7.	2003/0050228	03/13/2003	Ekwuribe et al.	A1		
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ADK	23.	5,681,567	10/28/1997	Martinez et al.	A		

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↑	25.	5,714,519	02/03/1998	Cincotta et al.	A		
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1		Document Number	Date	Country	Class	Subclass	Translation Yes No
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↑	38.	Allaudeen et al. "Orally Active Insulin: A Single Insulin Conjugate Selected for Future Studies" 60 th Annual Meeting of the American Diabetes Assoc., Atlanta, GA June 2000 (Abstract)					
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45.	Clement et al. "Effects of Multiple Doses of Orally Administered Hexyl Insulin M2 (HIM2) on Postprandial Blood Glucose (PPG) Concentrations in Type 1 Diabetic (T1) Patients" American Diabetes Association 62 nd Annual Meeting, June 2002 (Poster)		
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FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office		Attorney Docket Number 9233-46	Serial No. 10/075,097
LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)		Applicants: Ekwuribe et al.	
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63.		Puskas et al. "Investigation of Chymotrypsin Digestion Profile of Orally Active Insulin Conjugate HIM2" <i>AAPS Pharm. Sci.</i> 3(3) 2001 (Abstract)	
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72.		Soltero et al. "Pharmaceutical Compositions of Drug-Oligomer Conjugates and Methods of Treating Diseases Therewith" U.S. Serial No. 10/382,069, filed 03/05/2003	
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FORM PTO-1449 U.S. Department of Commerce Patent and Trademark Office LIST OF DOCUMENTS CITED BY APPLICANT (Use several sheets if necessary)		Attorney Docket Number 9233-46	Serial No. 10/075,097
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81. <i>Still, J. Gordon "Oral Insulin Development" Slide Presentation, VI International St.Barts Symposium Diabetes 2000: Therapy and Technology, London, England, May 12, 2000</i>			
82. <i>Stocklin et al. "A Stable Isotope Dilution Assay for the In Vivo Determination of Insulin Levels in Humans by Mass Spectrometry" Diabetes 46(1):1-7 (Jan. 1997)</i>			
83. <i>Tyle, Praveen "Iontophoretic Devices for Drug Delivery" Pharmaceutical Research 3(6):318-326 (1986)</i>			
84. <i>Uchio et al. "Site-Specific Insulin Conjugates with Enhanced Stability and Extended Action Profile" Advanced Drug Delivery Reviews 35:289-306 (1999)</i>			
85. <i>Vreeland et al. "Molar Mass Profiling of Synthetic Polymers by Free-Solution Capillary Electrophoresis of DNA-Polymer Conjugates" Anal. Chem. 73(8):1795-1803 (2001)</i>			
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Filing Date: 02/13/02				Group 1646/634			

QUARTER
JAN 13 2003
PATENT & TRADEMARK OFFICE

U. S. PATENT DOCUMENTS							
Examiner Initial	Document Number	Date	Name	Class	Subclass	Filing Date if Appropriate	
<div style="position: relative; height: 100%;"> <div style="position: absolute; top: 0; left: 0; right: 0; bottom: 0; border-left: 1px solid black; border-right: 1px solid black;"></div> </div>	1.	3,919,411	11/11/75	Glass et al.			
	2.	3,256,153	06/14/66	Heimlech			
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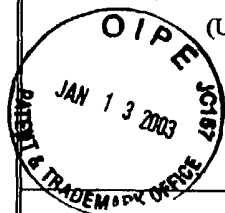
FORM PTO-1449 U.S. Department of Commerce
Patent and Trademark Office

Attorney Docket Number
9233-46

Serial No.
10/075,097

LIST OF DOCUMENTS CITED BY APPLICANT

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Applicants:

Ekwuribe et al.

Filing Date: 02/13/02

Group
1646

U.S. PATENT DOCUMENTS (CONT.)

1654

ADK	54.	5,324,775	06/28/94	Rhee et al.			
↑	55.	5,328,955	07/12/94	Rhee et al.			
	56.	5,359,030	10/25/94	Ekwuribe			
	57.	5,405,621	04/11/95	Sipos			
	58.	5,405,877	04/11/95	Greenwald et al			
	59.	5,413,791	05/09/95	Rhee et al.			
	60.	5,415,872	05/16/95	Sipos			
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	62.	5,444,041	08/22/95	Owen et al.			
	63.	5,446,091	08/29/95	Rhee et al.			
	64.	5,457,066	10/10/95	Frank et al.			
	65.	5,461,031	10/24/95	De Felippis			
	66.	5,468,478	11/21/95	Saifer et al.			
	67.	5,504,188	04/02/96	Baker et al.			
	68.	5,506,203	04/09/96	Backstrom et al.			
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	70.	5,523,348	06/04/96	Rhee et al.			
	71.	5,529,915	06/25/96	Phillips et al.			
	72.	5,550,188	08/27/96	Rhee et al.			
	73.	5,545,618	08/13/96	Buckley et al.			
	74.	5,567,422	10/22/96	Greenwald			
	75.	5,606,038	02/25/97	Regen			
	76.	5,612,460	03/18/97	Zalipsky			
	77.	5,631,347	05/20/97	Baker et al.			
	78.	5,637,749	06/10/97	Greenwald			
	79.	5,646,242	07/08/97	Baker et al.			
	80.	5,650,388	07/22/97	Shorr et al.			
ADK	81.	5,658,878	08/19/97	Backstrom et al.			

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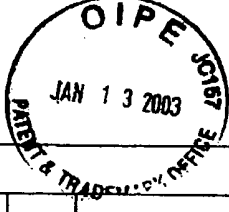
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ADK	83.	5,681,811	10/28/97	Ekwuribe
	84.	5,693,609	12/02/97	Baker et al.
	85.	5,693,769	12/02/97	Kahne et al.
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	87.	5,707,648	01/13/98	Yiv
	88.	5,738,846	04/14/98	Greenwald et al.
	89.	5,747,445	05/05/98	Backstrom et al.
	90.	5,747,642	05/05/98	De Felippis
	91.	5,750,497	05/12/98	Havelund et al.
	92.	5,766,620	06/16/98	Heiber et al.
	93.	5,824,638	10/20/98	Burnside et al.
	94.	5,830,853	11/03/98	Backstrom et al.
	95.	5,830,918	11/03/98	Sportsman et al.
	96.	5,849,860	12/15/98	Hakimi et al.
	97.	5,853,748	12/29/98	New
	98.	5,854,208	12/29/98	Jones et al.
	99.	5,856,451	01/05/99	Olsen et al.
	100.	5,866,538	02/02/99	Norup et al.
	101.	5,874,111	02/23/99	Maitra et al.
	102.	5,898,028	04/27/99	Jensen et al.
	103.	5,902,588	05/11/99	Greenwald et al.
	104.	5,905,140	05/18/99	Hansen
	105.	5,907,030	05/25/99	Shen et al.
	106.	5,922,675	07/13/99	Baker et al.
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ADK	108.	5,942,248	08/24/99	Barnwell
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				Applicants: Ekwuribe et al.			
				Filing Date: 02/13/02		Group 1646	
U.S. PATENT DOCUMENTS (CONT.)							
ADL	110.	5,952,008	09/14/99	Backstrom et al.			
↑	111.	5,952,297	09/14/99	De Felippis et al.			
	112.	5,962,267	10/05/99	Shin et al.			
	113.	5,968,549	10/19/99	New et al.			
	114.	5,969,040	10/19/99	Hallahan et al.			
	115.	5,981,709	11/09/99	Greenwald et al.			
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	117.	6,004,574	12/21/99	Backstrom et al.			
	118.	6,025,325	02/15/00	Campfield et al.			
	119.	6,034,054	03/07/00	De Felippis et al.			
	120.	6,043,214	03/28/00	Jensen et al.			
	121.	6,051,551	04/18/00	Hughes et al.			
	122.	6,063,761	05/16/00	Jones et al.			
	123.	6,093,391	07/25/00	Kabanov et al.			
	124.	6,113,906	09/05/00	Greenwald et al.			
	125.	6,165,976	12/26/00	Backstrom et al.			
	126.	6,177,087	01/23/01	Greenwald et al.			
	127.	6,191,105	02/20/01	Ekwuribe et al.			
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	133.	6,268,335	07/31/01	Brader			
	134.	6,306,440	10/23/01	Backstrom et al.			
	135.	6,309,633	10/30/01	Ekwuribe et al.			
ADL	136.	6,310,038	10/30/01	Havelund			

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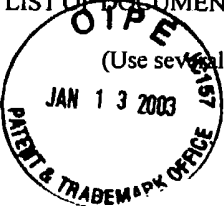
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				Applicants: Ekwuribe, et al.			
				Filing Date: 02/13/02		Group 1646 1654	
U.S. PATENT DOCUMENTS (CONT.)							
ADK ADK	137.	6,323,311	11/27/01	Liu et al.			
	138.	6,335,316	01/01/02	Hughes et al.			
FOREIGN PATENT DOCUMENTS							
		Document Number	Date	Country	Class	Subclass	Translation Yes No
	139.	GB 1 492 997	11/23/77	Great Britain			Yes
	140.	EP 0 031 567	07/08/81	EPO			Yes
	141.	JP 1 254 699	10/11/89	Japan			No
	142.	WO 93/01802	02/04/93	PCT			Yes - abstract
	143.	WO 95/09831	04/13/95	PCT			Yes
	144.	EP 0 483 465	08/02/95	EPO			Yes - claims
	145.	WO 95/30641	11/16/95	PCT			Yes
	146.	EP 0 597 007	10/16/96	EPO			Yes
	147.	EP 0 621 777	11/09/96	EPO			Yes - claims
	148.	WO 98/07745	02/26/98	PCT			Yes
	149.	EP 0 797 615	01/13/99	EPO			Yes
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		Applicants: Ekwuribe et al.		
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